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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,718	03/15/2001	Howard M. Johnson	UF-10164R	5517

29847 7590 07/13/2004

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EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/808,718	JOHNSON ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2004 and 01 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6, 8, 11-17 and 19-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8, 11-17 and 19-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The **examiner** of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michail Belyavskyi, Group Art Unit 1644, Technology Center 1600

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 05/20/04 and 07/01/04 have been entered.

Claims 1-6, 8, 11-17 and 19-26 are pending.

In view of the amendment, filed 05/20/04 and 07/01/04 the following rejections remain:

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 9, 11, and 14-17 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Kominsky et al. (2000, IDS) for the same reasons set forth in the previous Office Action, mailed 01/16/04.

Applicant's arguments filed on 05/20/04 and 07/01/04 have been fully considered but they are not persuasive.

Applicant asserts that he will provide a declaration to support the fact that they were in possession of the invention prior to the publication of the Kominsky et al reference.

It is noted however, that Applicant has not provided said declaration, thus rejection is maintained until such declaration is submitted.

5. Claims 1-6, 8, 11-17 and 19-26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 98/26747 (1998, IDS) for the same reasons set forth in the previous Office Action, mailed 01/16/04.

Applicant's arguments filed on 05/20/04 and 07/01/04 have been fully considered but they are not persuasive.

Applicant asserts that: (i) it is reasonable to conclude that the author of the '474 publication seems to be under the misapprehension that administering an antigen and administering a superantigen separately and at a later time, produces anergy not enhances the cellular immune response , as claimed in the present application, thus WO '707 teaching that anergy, not an immune response is achieved by the separate and later administration of superantigen after administering of the antigen; the WO'747 does not teach or contemplated a method of administering a superantigen for the purpose of preventing the onset of tumor development.

Contrary to Applicant's assertion, as was stated in the previous Office Action, WO '747 teaches a method for achieving superantigen mediated expansion of antigen-specific T cells for cancer treatment/prophylaxis which comprises administering a tumor specific antigen composition, including melanoma specific antigen followed by administration of a superantigen (SEA/SEB) composition at an optimized time interval following said administering of said tumor specific antigen composition to maximize the cellular immune response to said antigen (see particularly pages, 2, 18-19 and pages 6 (superantigens) and 8 (tumor antigens)). WO' 747 teaches that the optimal timing between immunization with cancer antigen and further administration of superantigen may be anywhere in the range of from minutes to up about two weeks , varing in accordance with the specific disease and the specific combination of the therapeutic agents. (see pages 19 and 72 in particular) . WO' 747 explicitly teaches that the present invention relates to the discovery that the clinical effects of an activated T cell in response to tumor antigen is exceeds when tumor antigen administered following by superantigen administration. Selected superantigens are capable of massively activating certain T-cell with defined TCR expression(seee page 20 in particular). Clearly, contrary to Applicant's assertion, WO'707 teaches that the method of the invention can be used to induced T cellular immune response, not anergy, for cancer treatment, including melanoma development (see pages 7 –8, and 77 in particular). This is further evidenced by the fact that WO'747 directly teachers the ways of preventing the anergy, when using the methods of the invention (see overlapping pages 73 and 74 in particular). In addition, contrary to Applicants assertion, WO'747 clearly stated that the method of the invention can be used for tumor vaccination (see page 69 in particular). Clearly, WO'747 contemplated a method of administering a superantigen for the purpose of preventing the onset of tumor development. However, it is noted that the amended claims do not recites a method of protecting or preventing the onset of melanoma. Thus is clear that both the prior art and applicant administer the same treatment, i.e. administration of melanoma specific antigen followed by administration of a superantigen composition at a optimized time interval, to the

same patients to achieve the same results, i.e. expansion of antigen-specific T cell and delaying the onset of tumor development.

The reference clearly anticipates the claimed invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kominsky et al. (2000, IDS) for the same reasons set forth in the previous Office Action, mailed 01/16/04.

Applicant's arguments filed on 05/20/04 and 07/01/04 have been fully considered but they are not persuasive.

Applicant asserts that he will provide a declaration to support the fact that they were in possession of the invention prior to the publication of the Kominsky et al reference.

It is noted however, that Applicant has not provided said declaration, thus rejection is maintained until such declaration is submitted.

The following new grounds of rejection is necessitated by the amendments filed on 05/20/04 and 07/01/04 .

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

9. Claims 1-6, 8 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

The phrase " prior to melanoma development," claimed in claim 1, line 3 represent a departure from the specification and the claims as originally filed. The passages pointed by the applicant do not provide a clear support for the "prior to melanoma development,". The specification and the claims as originally field only support "A method for achieving superantigen mediated expansion of antigen-specific T cells for inducing an immune response against melanoma which comprises administering a melanoma..."

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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July12, 2004

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